Complete Summary

GUIDELINE TITLE

Diagnosis and management of type 2 diabetes mellitus in adults.

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Diagnosis and management of type 2 diabetes mellitus in adults. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2008 Mar. 89 p. [126 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Institute for Clinical Systems Improvement (ICSI). Management of type 2 diabetes mellitus. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2006 Nov. 82 p.

**** REGULATORY ALERT ****

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- February 26, 2008, Avandia (rosiglitazone): A new Medication Guide for Avandia must be provided with each prescription that is dispensed due to the U.S. Food and Drug Administration's (FDA's) determination that this medication could pose a serious and significant public health concern.
- December 12, 2007, Carbamazepine: The U.S. Food and Drug Administration (FDA) has provided recommendations for screening that should be performed on specific patient populations before starting treatment with carbamazepine.
- November 14, 2007, Avandia (rosiglitazone): New information has been added to the existing boxed warning in Avandia's prescribing information about potential increased risk for heart attacks.
- October 16, 2007, Byetta (exenatide): Amylin Pharmaceuticals, Inc. has agreed to include information about acute pancreatitis in the PRECAUTIONS section of the product label.
- August 14, 2007, Thiazolidinedione class of antidiabetic drugs: Addition of a boxed warning to the updated label of the entire thiazolidinedione class of antidiabetic drugs to warn of the risks of heart failure.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Prediabetes (hyperglycemia not sufficient to meet the diagnostic criteria for diabetes)
- Type 2 diabetes mellitus

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Prevention
Treatment

CLINICAL SPECIALTY

Cardiology
Endocrinology
Family Practice
Internal Medicine
Nephrology
Neurology
Nutrition
Ophthalmology
Podiatry

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Dietitians
Health Care Providers
Health Plans
Hospitals

Managed Care Organizations
Nurses
Patients
Physician Assistants
Physicians
Podiatrists

GUIDELINE OBJECTIVE(S)

- To provide a comprehensive approach to the diagnosis and management of prediabetes and type 2 diabetes mellitus in adults. Management will include nutrition therapy, physical activity, self-management strategies, and pharmacologic therapy recommendations, as well as prevention and diagnosis of diabetes-associated complications and risk factors.
- To increase the percentage of adult patients, age 18 to 75 with type 2 diabetes mellitus, who achieve established control around comprehensive measures
- To increase the percentage of adult patients, age 18 to 75 with type 2 diabetes mellitus, for whom recommended screening frequencies and ideal treatment goals are met
- To decrease the percentage of adult patients, age 18 to 75 with type 2 diabetes mellitus, with poorly controlled blood sugars and cardiovascular risk factors
- To improve self-management skills in adult patients, age 18 to 75 with type 2 diabetes mellitus

TARGET POPULATION

Adult patients age 18 and over with prediabetes or type 2 diabetes mellitus

Note: The diagnosis of gestational diabetes or the management of diabetes in patients who are pregnant is excluded from the scope of this guideline. (Refer to the National Guideline Clearinghouse [NGC] summary of the Institute for Clinical Systems Improvement [ICSI] guideline Routine Prenatal Care for information relating to gestational diabetes). Also, the diagnosis and management of type 1 diabetes is not included in this guideline.

INTERVENTIONS AND PRACTICES CONSIDERED

Prevention

1. Laboratory tests including fasting plasma glucose or oral glucose tolerance test (OGTT)
2. Patient education including lifestyle behavior changes, nutrition counseling, and cardiovascular risk reduction
3. Monitoring and follow-up testing as indicated
4. Pharmacologic therapy including biguanides, alpha glucosidase inhibitors, angiotensin-converting enzyme (ACE) inhibitors, and thiazolidinediones. (Note: None of these treatments have proven to be as effective as lifestyle change.)

Diagnosis

Detailed medical history, physical examination and confirmatory laboratory testing (refer to "Major Recommendations" section)

Treatment/Management

1. Pharmacologic therapy including:
    - Glycemic management
        - Individualized insulin therapy based on patient's lifestyle, treatment goals, and self-monitoring blood glucose (SMBG)
        - Non-insulin agents: Metformin (first choice), second-generation sulfonylureas and glitazones (secondary choices); other oral agents, such as alpha glucosidase inhibitors, dipeptidyl peptidase-4 (DPP-4) inhibitor, meglitinides, thiazolidinediones, glucagon-like peptide 1 agonist, and synthetic analog of human amylin, if first and secondary choices not tolerated or contraindicated
        - Combinations of oral agents with other oral agents or insulin
    - Blood pressure control
        - Angiotensin-converting enzyme (ACE) inhibitors and angiotensin II receptor blockers (ARBs)
        - Thiazide diuretics
        - Lipid management
            - Statins

2. Self-management programs including:
    - Nutrition therapy program
    - Physical activity program (preceded by medical assessment of physical conditions, limitations, risk of cardiovascular disease, cardiac stress testing and blood glucose control)

3. Patient education for self-management, including disease process, prevention of complications, risk reduction, medication compliance, foot care and available community resources
4. Other measures to reduce cardiovascular risk: aspirin use, tobacco cessation
5. Ongoing assessment for complications; treatment and/or referral for complications as appropriate

MAJOR OUTCOMES CONSIDERED

Morbidity and mortality associated with type 2 diabetes mellitus and/or complications

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A literature search of clinical trials, meta-analyses, and systematic reviews is performed.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion. Individual studies are classed according to the system presented below, and are designated as positive, negative, or neutral to reflect the study quality.

Conclusion Grades:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results of different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

Study Quality Designations

The quality of the primary research reports and systematic reviews are designated in the following ways on the conclusion grading worksheets:

Positive: indicates that the report or review has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis.

Negative: indicates that these issues (inclusion/exclusion, bias, generalizability, and data collection and analysis) have not been adequately addressed.

Neutral: indicates that the report or review is neither exceptionally strong nor exceptionally weak.

Not Applicable: indicates that the report is not a primary reference or a systematic review and therefore the quality has not been assessed.

Classes of Research Reports:

A. Primary Reports of New Data Collection:

Class A:

- Randomized, controlled trial

Class B:

- Cohort study

Class C:

- Non-randomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D:

- Cross-sectional study
- Case series
- Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports:

Class M:

- Meta-analysis
- Systematic review
- Decision analysis
- Cost-effectiveness analysis

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

- Medical opinion

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Each guideline, order set, and protocol is developed by a 6- to 12-member work group that includes physicians, nurses, pharmacists, other healthcare professionals relevant to the topic, along with an Institute for Clinical Systems Improvement (ICSI) staff facilitator. Ordinarily, one of the physicians will be the leader. Most work group members are recruited from ICSI member organizations, but if there is expertise not represented by ICSI members, 1 or 2 members may be recruited from medical groups or hospitals outside of ICSI.

The work group will meet for seven to eight three-hour meetings to develop the guideline. A literature search and review is performed and the work group members, under the coordination of the ICSI staff facilitator, develop the algorithm and write the annotations and footnotes and literature citations.

Once the final draft copy of the guideline is developed, the guideline goes to the ICSI members for critical review.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

The guideline developers reviewed published cost analyses.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Critical Review Process

Every newly developed guideline or a guideline with significant change is sent to the Institute for Clinical Systems Improvement (ICSI) members for Critical Review. The purpose of critical review is to provide an opportunity for the clinicians in the member groups to review the science behind the recommendations and focus on the content of the guideline. Critical review also provides an opportunity for clinicians in each group to come to consensus on feedback they wish to give the work group and to consider changes necessary across systems in their organization to implement the guideline.

All member organizations are expected to respond to critical review guidelines. Critical review of guidelines is a criterion for continued membership within the ICSI.

After the critical review period, the guideline work group reconvenes to review the comments and make changes, as appropriate. The work group prepares a written response to all comments.

Approval

Each guideline, order set, and protocol is approved by the appropriate steering committee. There is one steering committee each for Respiratory, Cardiovascular, Women's Health, and Preventive Services. The Committee for Evidence-based Practice approves guidelines, order sets, and protocols not associated with a particular category. The steering committees review and approve each guideline based on the following:

- Member comments have been addressed reasonably.
- There is consensus among all ICSI member organizations on the content of the document.
- Within the knowledge of the reviewer, the scientific recommendations within the document are current.
- Either a critical review has been carried out, or to the extent of the knowledge of the reviewer, the changes proposed are sufficiently familiar and sufficiently agreed upon by the users that a new round of critical review is not needed.

Once the guideline, order set, or protocol has been approved, it is posted on the ICSI Web site and released to members for use. Guidelines, order sets, and protocols are reviewed regularly and revised, if warranted.

Revision Process of Existing Guidelines

ICSI scientific documents are revised every 12 to 36 months as indicated by changes in clinical practice and literature. Every 6 months, ICSI checks with the work group to determine if there have been changes in the literature significant enough to cause the document to be revised earlier than scheduled.

Prior to the work group convening to revise the document, ICSI members are asked to review the document and submit comments. During revision, a literature search of clinical trials, meta-analysis, and systematic reviews is performed and reviewed by the work group. The work group will meet for 1-2 three-hour meetings to review the literature, respond to member organization comments, and revise the document as appropriate.

If there are changes or additions to the document that would be unfamiliar or unacceptable to member organizations, it is sent to members to review prior to going to the appropriate steering committee for approval.

Review and Comment Process

ICSI members are asked to review and submit comments for every guideline, order set, and protocol prior to the work group convening to revise the document.

The purpose of the Review and Comment process is to provide an opportunity for the clinicians in the member groups to review the science behind the recommendations and focus on the content of the order set and protocol. Review and Comment also provides an opportunity for clinicians in each group to come to consensus on feedback they wish to give the work group and to consider changes needed across systems in their organization to implement the guideline.

All member organizations are encouraged to provide feedback on order sets and protocol, however responding to Review and Comment is not a criterion for continued membership within ICSI.

After the Review and Comment period, the work group reconvenes to review the comments and make changes as appropriate. The work group prepares a written response to all comments.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse (NGC) and the Institute for Clinical Systems Improvement (ICSI): For a description of what has changed since the previous version of this guidance, refer to Summary of Changes Report -- March 2008.

The recommendations for the diagnosis and management of type 2 diabetes mellitus in adults are presented in the form of 4 algorithms with a total of 35 components, accompanied by detailed annotations. Algorithms are provided for: Diagnosis and Management of Type 2 Diabetes Mellitus in Adults, Glycemic Control, Blood Pressure Control, and Ongoing Management; clinical highlights and selected annotations (numbered to correspond with the algorithm) follow.

Class of evidence (A-D, M, R, X) and conclusion grade (I-III, Not Assignable) definitions are repeated at the end of the "Major Recommendations" field.

Clinical Highlights

- Self-management support is necessary for people with diabetes to manage their disease. *(Annotation #10)*
- Focus on cardiovascular risk reduction (blood pressure control, low-density lipoprotein (LDL) cholesterol control and statin use, aspirin use, and tobacco cessation). *(Annotation #11)*.
- Glycosylated hemoglobin (A1c) levels should be individualized to the patient. *(Annotations #11, 15, 16, 17, 19, 20, 22) (see original guideline document for annotation #20)*.
- Aggressive blood pressure control is just as important as glycemic control. Systolic blood pressure level should be the major factor for detection, evaluation, and treatment of hypertension. The use of two or more blood pressure lowering agents is often required to meet blood pressure goal. *(Annotations #11, 23, 24, 25, 26, 28)*.
- Prevent microvascular complications through annual eye exams, foot risk assessments and foot care counseling, and annual screening for proteinuria. *(Annotations #13, 32)*.
- Initial therapy with lifestyle treatment and metformin is advised unless contraindicated. *(Annotations #4, 10)*

Diagnosis and Management of Type 2 Diabetes Mellitus in Adults Algorithm Annotations

1. **Diagnostic Testing for Diabetes or Prediabetes**

   Prediabetes is now the term recommended for patients with impaired glucose tolerance or impaired fasting glucose. Type 2 diabetes is frequently not diagnosed until complications appear, and approximately one-third of all people with diabetes may be undiagnosed *[R]*.

   Patients presenting with symptoms of diabetes should be tested. Possible screening tests for these conditions include a fasting plasma glucose or an oral glucose tolerance test. Testing patients with hypertension, dyslipidemia, and heart disease is also recommended. Other patients at risk for diabetes are also appropriate for testing.

   See the NGC summaries of the ICSI guidelines: Hypertension Diagnosis and Treatment, Lipid Management in Adults, Preventive Services for Adults, Prevention and Management of Obesity (Mature Adolescents and Adults), and Stable Coronary Artery Disease).

2. **Evaluation of Patients with Elevated Glucose**

   Evaluation may be completed in one or more visits over a reasonably short period of time. Clinical judgment is needed to determine the urgency of completing the evaluation.

   History *[R]*

   - Symptoms
   - Eating habits, weight history
   - Physical activity

- Prior or current infections, particularly skin, foot, dental, and genitourinary
- Symptoms and treatment of chronic complications associated with diabetes: eye, heart, kidney, nerve, genitourinary (including sexual function), peripheral vascular, and cerebrovascular (these may be present at diagnosis)
- Current medications including over-the-counter (OTC) medications, dietary supplements and alternative therapies with a focus on medications known to induce diabetes-type states (e.g., steroids, atypical antipsychotics)
- Risk factors for diabetes include:
    - Risk factors for atherosclerosis: smoking, hypertension, dyslipidemia
    - Family history of diabetes, cardiovascular disease, cerebrovascular disease, hyperlipidemia
    - Gestational history of an infant weighing more than 9 pounds, toxemia, stillbirth, or previous diagnosis of gestational diabetes
- Psychosocial, cultural, and economic factors that might influence the management of diabetes
- Alcohol/drug use

Physical Examination *[R]*

- Weight, height, body mass index (BMI), blood pressure
- Cardiovascular system: heart, blood pressure, peripheral vascular circulation including pulses and bruits (abdominal, carotid, femoral)
- Feet: nails, web spaces, ulcers, pulses, calluses, structural deformities, protective sensation and shoes
- Other examinations as guided by the patient's symptoms and/or concerns:
    - Skin: infections or diseases such as acanthosis nigricans, xanthoma
    - Neurological symptoms: sensory state of hands and feet, muscle wasting, deep tendon reflexes
    - Mental health: screen for depression and/or anxiety
    - Referral to an eye specialist to assess optic health
    - Referral to a dentist to assess oral health

Laboratory Evaluation

- Fasting plasma glucose or random plasma glucose
- A1C (not required for prediabetes)
- Fasting lipid profile: total cholesterol, high-density lipoprotein (HDL cholesterol), LDL cholesterol, and triglycerides
- Serum creatinine and liver function test (alanine transaminase [ALT] and aspartate transaminase [AST])
- Urine: ketones, glucose, protein, microalbuminuria, culture (if microscopic is abnormal or symptoms of infection present)

  Urine microalbumin tests can identify patients with early diabetic nephropathy when intervention may be most effective in delaying or preventing end stage renal disease (ESRD). Single tests for urinary

microalbumin and urinary creatinine can accurately detect urinary microalbumin excretion.

For more information see Annotation #32, "Annual Assessment of Complications." *[B]*, *[R]*

Increased urinary microalbumin is a predictor of increased cardiovascular mortality *[R]*.

3. **Diagnosis of Prediabetes**
    - Fasting plasma glucose of 100 mg/dL to 125 mg/dL
    - Oral glucose tolerance test (OGTT) two-hour plasma glucose: 140 mg/dL to 199 mg/dL *[R]*

4. **Treatment of Prediabetes**

Patients who are identified with prediabetes should be referred for education and lifestyle interventions. Health care providers should follow up with patients diagnosed with prediabetes on an annual basis to monitor their progress and review treatment goals *[R]*.

Intensive lifestyle change or programs have been proven effective in delaying or preventing the onset of diabetes by about 50%. Effective lifestyle changes include setting achievable goals, obtaining weight loss when needed (ideally at least 5% total body weight), and increasing physical activity *[A]*.

The following treatments are recommended for people with prediabetes:

- Intensive lifestyle behavioral change including a nutrition and activity plan by a registered dietitian, health educator, or other qualified health professional. Ongoing support of behavioral change is necessary.
- Cardiovascular risk reduction appropriate to the needs of the individual

Patients who meet treatment goals:

- Annual follow-up and reassessment of risks for developing diabetes *[A]*, *[R]*.

Patients who are not meeting treatment goals:

- Intensify education and counseling on lifestyle interventions.
- There is some evidence of prevention of diabetes through pharmacotherapy with biguanides and alpha glycosidase inhibitors *[A]*, *[M]*. Rosiglitazone has been shown to prevent diabetes, but the risk of congestive heart failure was increased *[A]*. Lifestyle change remains the preferred method to prevent diabetes *[A]*, *[M]*.

5. **Diagnosis of Type 2 Diabetes**

Diagnosis of type 2 diabetes *[R]*

- Fasting plasma glucose greater than or equal to 126 mg/dL
- Casual plasma glucose greater than or equal to 200 mg/dL plus typical symptoms of diabetes
- In the absence of unequivocal hyperglycemia associated with acute metabolic decompensation, the results should be confirmed by repeat testing on a different day. At the present time A1c should not be used to diagnose diabetes.

History

- Details of previous treatment programs, including diabetes education
- Current treatment of diabetes, including medications, nutrition, physical activity patterns, and results of glucose monitoring
- Frequency, severity, and cause of acute complications such as hypoglycemia, hyperglycemia and non-ketotic hyperosmolar coma

6. **Should Patient Be Hospitalized?**

Inpatient care may be appropriate in the following situations *[R]*:

- Elderly patients with infection or illness, weight loss, dehydration, polyuria or polydipsia
- Life-threatening acute metabolic complications of diabetes:
    - Hyperglycemic hyperosmolar state with impaired mental status, elevated plasma osmolality that includes plasma glucose greater than 600 mg/dL
    - Diabetic ketoacidosis with a plasma glucose greater than 250 mg/dL, arterial pH less than 7.30 and serum bicarbonate level less than 15 mEq/L and the presence of moderate ketonuria and/or ketonemia
    - Hypoglycemia with neuroglycopenia that includes blood glucose less than 50 mg/dL and treatment has not resulted in prompt recovery, coma, seizures or altered behavior.
- Uncontrolled insulin-requiring diabetes during pregnancy
- Surgery, infection, steroids – if these conditions cause significant hyperglycemia and rapid initiation of rigorous glucose is needed

7. **Inpatient Diabetes Management**

Diabetic inpatients suffer increased morbidity, mortality, length of stay, and other related hospital costs compared to non-hyperglycemic inpatients. These negative outcomes are observed more frequently in hospitalized patients with newly discovered hyperglycemia. Hyperglycemia is an independent marker of inpatient mortality in patients with undiagnosed diabetes *[B]*.

Hyperglycemia has been associated with increased infection rates and poorer short-term and long-term outcomes in critically ill patients in the intensive care unit (ICU), post-myocardial infarction (MI), and postsurgical settings. Studies support that aggressive glucose management in medical and surgical patients can improve outcomes *[A]*.

The following are recommended in the inpatient setting *[R]*:

- Intensive insulin therapy with intravenous insulin in critically ill patients *[R]*
- Use of scheduled insulin, with basal coverage (improves glucose control compared to sliding scale coverage alone)
- For insulin-deficient patients, despite reductions or the absence of caloric intake, basal insulin must be provided to prevent diabetic ketoacidosis.
- Target preprandial plasma glucose levels are 90 to 130 mg/dL *[R]*
- If measured, the target postprandial plasma glucose is less than 180 mg/dL *[R]*
- Establishing a multidisciplinary team that sets and implements institutional guidelines, protocols, and standardized order sets for the hospital results in reduced hypoglycemic and hyperglycemic events.

Other considerations include *[R]*:

- For patients who are alert and demonstrate accurate insulin self-administration and glucose monitoring, insulin self-management should be allowed as an adjunct to standard nurse-delivered diabetes management.
- Patients with no prior history of diabetes who are found to have hyperglycemia (random blood glucose greater than 125 mg/dL or random glucose of 200 mg/dL) during hospitalization should have follow-up testing for diabetes within one month of hospital discharge *[B]*.

Please see ICSI's Subcutaneous Insulin Management Order Set for additional information regarding inpatient glucose management.

8. **Does Patient Need Outpatient Stabilization?**

Indications for immediate insulin treatment in type 2 diabetes mellitus *[R]*:

- Severe symptoms, marked weight loss, polyuria, polydipsia
    - Fasting plasma glucose greater than 300 mg/dL fasting, or
    - Random glucose over 350 mg/dL, or
    - A1c over 10%, or
    - Presence of ketonuria

Insulin therapy may not be permanent once patient is stabilized.

9. **Initial Stabilization for Outpatients Requiring Immediate Insulin Treatment**

If the patient presents and is considered stable enough for outpatient care but meets indications noted above for starting insulin, the work group offers several acceptable ways of initiating insulin.

- One example is to calculate the total daily dose of insulin at 0.3 units/kg and start bedtime glargine at 50% of the total dose, splitting the remaining 50% with short- acting insulin before meals.
- Another example is to start an oral agent while simultaneously initiating glargine at a dose of approximately 0.1 units/kg.
- A third example is to calculate the total daily dose of insulin at 0.3 units/kg and use pre-mixed insulin with 2/3 the dose in the a.m. and 1/3 in the p.m.

At presentation, all patients should be instructed on blood glucose monitoring, hypoglycemia recognition and treatment, and how/when to contact health care support. Patients should check blood sugars frequently when insulin is initiated. Patients should receive daily phone or visit contact for at least three days and have 24-hour emergency phone support if needed.

Patients should be referred for nutrition and diabetes education and be seen in a timely way after diagnosis, (e.g., within one to seven days).

Insulin therapy may not be permanent, particularly if oral agents are added or if, at presentation, the patient is in metabolic stress such as infections, acute metabolic complications, recent surgery *[D]*. As the metabolic stress resolves, the insulin dose requirements may rapidly fall.

For the occasional unstable patient with type 2 diabetes, maximal doses of oral hypoglycemic agents may afford an approach to the patient who is psychologically resistant to or refuses insulin initiation.

10. **Recommend Self-Management Program**

Nutrition Therapy

Medical nutrition therapy for diabetes emphasizes improving metabolic outcomes. Major goals are to attain and maintain in the normal or as close to normal range as is safely possible blood glucose, blood pressure, and lipid/lipoprotein levels. These goals help reduce the risk for chronic complications of diabetes and macro- and microvascular disease *[D]*, *[R]*.

Weight loss is also an important goal because it improves insulin-resistance, glycemic control, blood pressure, and lipid profiles. Moderate weight loss (5% of body weight) can improve fasting blood glucose in many overweight or obese persons *[R]*. Low-carbohydrate diets, restricting total carbohydrate to less than 130 g/day, are not recommended in the management of diabetes.

There is considerable interest in low-carbohydrate diets for weight loss; however, the long-term effects of these diets are unknown and although such diets produce short-term weight loss, maintenance of weight loss is similar to that of low-fat diets, and impact on cardiovascular disease risk profile is uncertain *[R]*.

See the ICSI Technology Assessment Report #83, Diet Programs for Weight Loss in Adults and the NGC summary of the ICSI guideline Prevention and

Management of Obesity [Mature Adolescents and Adults] for more information.

Appropriate nutrition therapy will be developed collaboratively with the person who has diabetes. Instruction may require a provider with expertise in medical nutrition therapy, and instruction may be obtained through individual or group consultation *[A]*, *[M]*, *[R]*. It is important that physicians understand the general principles of medical nutrition therapy and support them for patients with diabetes. In most people, nutrition recommendations are similar to those of the general population. **Medical nutrition therapy is a Medicare Part B covered benefit**.

- Evaluate the patient's current eating habits and modify as needed. Recommend:
    - Working together toward gradual, realistic and culturally appropriate lifestyle change goals.
    - Maintaining the pleasure of eating by limiting only food choices indicated by scientific evidence.
    - Healthful food choices: foods containing carbohydrates from whole grains, fruits, vegetables, legumes and low-fat dairy products should be included in a healthy eating plan.
    - Reducing total caloric intake by moderating food/beverage and limiting total fat intake.
    - Distributing carbohydrates evenly throughout the day to smaller meals and snacks.
    - Monitoring carbohydrates remains a key strategy in achieving glycemic control, whether by carbohydrate counting, exchanges or experience-based estimation *[R]*.
    - If one chooses to drink alcohol and has not been cautioned against it, limit intake to one drink per day for women and two drinks per day for men, according to USDA guidelines a drink is defined as 12 oz. of regular beer, 5 oz. of wine, or 1.5 oz. of 80-proof distilled spirits. To reduce the risk of hypoglycemia, alcohol should be consumed with food.
- Individualize the nutrition prescription based on the nutrition assessment and treatment goals of each patient. For example, if the patient has been eating 45% of calories from fat, lowering fat to even 40% can be helpful.

Carbohydrate *[R]*

- Total amount of carbohydrate is more important than the source and type of starch or sugar.
- Sucrose (e.g., table sugar) and sucrose-containing foods do not need to be restricted. However, they should be substituted for other carbohydrate sources, or if added, covered with insulin or other glucose-lowering medication. They should be eaten within the context of a healthy diet.
- Added fructose as a sweetening agent is not recommended as it may adversely affect plasma lipids. Naturally occurring fructose in fruits, vegetables and other foods does not need to be avoided.

- The use of sugar alcohols, such as sorbitol or mannitol in small amounts, appears to be safe; however, they may cause gastrointestinal side effects.
- Non-nutritive sweeteners are safe when consumed within the acceptable daily intake levels established by the U.S. Food and Drug Administration (FDA).
- Encourage consuming a wide variety of fiber-containing foods such as legumes, fiber-rich cereals, fruits, vegetables and whole grain products to achieve fiber intake goals of 14 g/1,000 calories.
- The use of glycemic index and load may provide a modest additional benefit over that observed when total carbohydrate is considered alone.

Protein *[R]*

- 15% to 20% of the total calories. Avoid protein intakes of greater than 20% of total daily energy. The long-term effects of consuming more than 20% of energy as protein on the development of nephropathy have not been determined.
- Reduction of protein intake to 0.8-1.0 g/kg in individuals with diabetes in the earlier stages of chronic kidney disease (CKD) and to 0.8 g/kg in the later stages of chronic kidney disease is recommended and may improve measures of renal function (urine albumin excretion rate, glomerular filtration rate).
- Protein does not increase plasma glucose concentrations but does increase serum insulin responses, and thus protein should not be used to treat acute or prevent nighttime hypoglycemia.

Fat *[R]*

- Patients with normal weight and lipids: continue maintaining healthy weight and lipids that include less than or equal to 30% calories from fat, less than 7% saturated fats, limit of trans fats, and less than 200 mg cholesterol *[R]*.
- To lower LDL cholesterol, energy derived from saturated fat can be reduced if weight loss is desirable or replaced with either carbohydrate or monounsaturated fat when weight loss is not a goal.
- Weight control: balance lower fat and caloric consumption with regular physical activity of 30 minutes most days.
- Patients with elevated cholesterol and LDL cholesterol: implement National Cholesterol Education Program-Therapeutic Lifestyle (TLC) recommendations. TLC diet: reduce saturated fat to less than 7% calories and cholesterol to less than 200 mg, consider increased soluble fiber intake (10 to 25 g/day) and plant stanols/sterols (2 g/day), and minimize trans fat intake.
- Two or more servings of fish per week (with the exception of commercially fried fish fillets) provide n-3 polyunsaturated fatty acids and are recommended.
- Patients with elevated triglycerides: improve blood glucose control, encourage weight loss, increase physical activity, avoid alcoholic beverages, moderate carbohydrate intake and limit dietary saturated fat.

Sodium *[R]*

- Medical nutrition therapy for hypertension control focuses on weight reduction and recommended sodium intakes of 2,300 mg/day for normotensive and hypertensive individuals and a sodium intake less than 2,000 mg/day for patients with diabetes and symptomatic heart failure. Additional recommendations include consuming five to nine servings of fruits and vegetables daily, and two to four daily servings of low-fat dairy products rich in calcium, magnesium and potassium.

Structured programs that emphasize lifestyle changes including education, reduced energy and fat intake (approximately 30% of total energy), regular physical activity and frequent participant contact are necessary to produce long-term weight loss of 5% to 7% of starting weight. Lifestyle change should be the primary approach to weight loss *[R]*.

When usual measures to promote weight loss are unsuccessful in severely obese individuals with comorbidities, there may be a role for adjunctive pharmacotherapy or surgical procedures.

There is some evidence that pharmacotherapy for weight loss may offer short-term benefit for a subset of patients with type 2 diabetes *[A]*. The studies, however, were of relatively weak design, and pharmacotherapy for weight loss cannot be recommended for most patients with type 2 diabetes.

Bariatric surgery has recently been discussed as an option for some individuals with type 2 diabetes who have a BMI of 35 kg/m^2 or more. Bariatric surgery can result in marked improvements in glycemia; however, the long-term benefits and risks need to be studied further *[R]*.

Patients should be provided with ongoing nutrition self-management and care support *[A]*, *[M]*, *[R]*.

Physical Activity

The positive benefits of physical activity include improved blood pressure values, improved lipid profile, improved cardiac status, increased insulin sensitivity, more effective weight management, and improved glycemic control, and it helps in the management of depressive symptoms. Because the positive effects of increased physical activity diminish within days of the cessation of exercise, regular activity is recommended *[D]*.

Recent studies indicate that cumulative daily physical activity may be almost as beneficial as continuous physical exertion *[A]*, *[R]*. The major emphasis is to gradually increase level of physical activity either by increasing duration or frequency.

Epidemiological studies suggest that regular aerobic physical activity is beneficial for the treatment of type 2 diabetes mellitus *[C]*, *[R]*.

Reinforce the ongoing need and benefits of physical activity at each visit, offering support and advice on ways to incorporate 30 minutes of physical activity into most days of the week *[R]*.

Strategies for Initiation of Increased Physical Activity

- Start by incorporating 10 minutes of increased activity into each day.
    - Use stairs instead of elevator.
    - Park car away from building entrance and walk.
    - Walk to do errands.
- Overcome barriers.
    - Self monitor activity performed using pedometer, time record, and/or journal.
    - Be consistent.
    - Have alternative activities for inclement weather.
    - Find enjoyable activities.
    - Be active at the time of day that is best for the individual.

Medical Evaluation to Assess Safety of Exercise Program

- Assess physical condition and limitations of the patient.
- Assess for cardiovascular disease. Atypical symptoms and painless ischemia are more common in patients with diabetes *[D]*.
- Cardiac stress testing: there is no evidence that stress testing is routinely necessary in asymptomatic people before beginning a moderate-intensity exercise program such as walking.
- Cardiac stress testing should be considered for the previously sedentary individuals at moderate to high-risk for cardiovascular disease who want to undertake vigorous aerobic exercise that exceeds the demands of everyday living *[R]*.
- Cardiac stress testing is particularly recommended for the previously sedentary diabetic individual with a ten-year risk of a coronary event of 10% or greater. This would correspond approximately to people with type 2 diabetes who meet any of the following criteria *[R]*:
    - Age 40, with or without cardiovascular disease risk factors other than diabetes.
    - Age 30 with additional risk factors including type 2 diabetes of ten years duration or more, hypertension, tobacco use, dyslipidemia, preproliferative retinopathy, or nephropathy including microalbuminuria.
    - The presence of known or suspected coronary artery disease, cerebral vascular disease, peripheral vascular disease, autonomic neuropathy or advanced nephropathy with renal failure regarding of the individual's age.
- Assess blood glucose control.
- Assess knowledge of physical activity in relation to blood glucose control.
- When making a referral, make other health care providers aware of limitations for exercise.

Physical activity can be intermittent or cumulative *[A], [R]*.

Intermittent

Frequency: 4 to 7 days/wk
Intensity: 55% to 69% predicted maximum heart rate
Time: Minimum of 8 to 10 minutes/session

Cumulative

Frequency: Physical activity every day (walking, taking stairs, housework, scheduled activity)
Intensity: Moderate activity (equivalent to brisk walk)
Time: Accumulate 30 minutes or more each day

Education for Self-Management

Adequate self-management support for patients requires integration of available self-management education and support resources into routine care. Usually appropriate education may require the expertise of the diabetes educator. This instruction can be obtained through individual or group consultation *[A]*, *[M]*, *[R]*. Medicare reimbursement for diabetes self-management training requires this service be provided by an education program that has achieved recognition by the American Diabetes Association; the staff in such a program is multidisciplinary and includes at least a registered dietician (RD) and a registered nurse (RN) with experiential preparation in education and diabetes management *[R]*. A number of studies involving a clinical pharmacist in programs with cardiac risk factors in select patients with diabetes have proven to be effective. Cultural sensitivity is an important aspect of education for self-management *[D]*. Providers should be aware of culturally appropriate educational and community resources to support persons with diabetes and their families.

An education plan should be identified based on the needs of the individual and referral made to either an internal or external education resource. Periodic reassessment of educational goals is recommended *[D]*, *[R]*.

(See the Support for Implementation Section in the original guideline document for a list of American Diabetes Association [ADA] recognized education programs available.)

Components of self-management include:

- Description of the diabetes disease process and treatment options
- Goal-setting to promote health, and problem-solving for daily living
- Preventing, detecting, and treating acute complications
- Preventing (through risk reduction behavior), detecting, and adhering to treatment for chronic complications
- Self-monitoring blood glucose, ketones (when appropriate), and using results to improve control
- Incorporation of appropriate nutrition management *[C]*
- Incorporation of physical activity into lifestyle *[C]*
- Utilizing medications (if applicable) for therapeutic effectiveness

- Awareness of culturally appropriate community resources/support for persons with diabetes mellitus and their families, and ability to access community resources
- Psychosocial adjustment of diabetes to daily life
- Promotion of preconception care, counseling, and management during pregnancy, if applicable

Community Resources

There is some evidence for the effectiveness of community-based diabetes self-management education and support. These programs may complement the care and education that are routinely part of standard medical practice, and may enhance a patient's ability to self-manage diabetes. The Task Force on Community Preventive Services, supported by the Centers for Disease Control and Prevention, recommends diabetes self-management education in community gathering places.

Foot Care

Education should be tailored to patient's current knowledge, individual needs and risk factors. Patients should be aware of their risk factors and appropriate measures to avoid complications *[R]*. (See Annotation # 32, "Annual Assessment of Complications, Comprehensive Foot Examination with Risk Assessment" below.)

Education should cover:

- Inspect feet daily for cuts, bruises, bleeding, redness, and nail problems.
- Wash feet daily and dry thoroughly including between the toes.
- Do not soak feet unless specified by a health care provider.
- Be careful of hot water.
- Use of lotions, Vaseline, or creams is acceptable, but do not use between the toes.
- Do not walk barefoot.
- Check shoes each day for objects that may have fallen inside, excessive wear, or areas that may cause irritation.
- Avoid injuries from cutting toenails, avoid self-cutting calluses or corns.
- When to seek care

11. **Standardized Treatment Goals**

Key Points:

- The following standardized treatment goals are recommended: A1c individualized to patient and blood sugars at goal, use of statins and titrating LDL cholesterol to goal of less than 100 mg/dL without coronary artery disease and less than 70 mg/dL with coronary artery disease, blood pressure less than 130/80 mmHg, daily aspirin for patients 40 years of age and over, and avoidance of tobacco use.

- Individual patients with special circumstances must have treatment goals based on the risks and benefits for that patient. The American Geriatric Society recommends A1c less than 8% for many patients, and the benefits of tight glucose control diminish for many patients with life expectancy less than five years.

The physician and patient must discuss and document the treatment goals and the plan to achieve the desired goals. Less strict goals may be established for the very elderly or for the patient with severe health problems (e.g., severe coronary artery disease, metastatic cancer, dementia, limited life expectancy from other causes).

Control of hyperglycemia is important; however, in older persons with diabetes, a greater reduction in morbidity and mortality may result from control of cardiovascular risk factors than from tight glycemic control *[R]*.

Factors to consider for individualized treatment goals:

- Advanced age or estimated survival of less than five years
- Cognitive impairment or advanced neurological disease such as stroke or dementia
- Polypharmacy concerns
- Multiple comorbidities
- Hypoglycemia unawareness, history of severe hypoglycemia requiring assistance
- Inability to recognize and treat hypoglycemia or the inability to comply with standard goals
- Duration of diabetes
- Cardiovascular risk

Goals for Glycemic Control -- A1c Individualized to Patient

Early evidence on the Action to Control Cardiovascular Risk in Diabetes (ACCORD) trial and the Steno 2 Study have further reinforced the need for individualization of glycemic management goals of patients with type 2 diabetes.

The Data Safety and Monitoring Board (DSMB) and the director of the National Heart, Lung, and Blood Institute (NHLBI) recommended that ACCORD intensive glycemia intervention participants (A1c goal <6.0%) be transitioned to standard glycemia treatment (A1c goal of 7%-7.9%) due to safety concerns. The ACCORD study found a 20% higher risk of all-cause mortality in the intensive treatment group (with an achieved median of 6.4%) than in the standard treatment group (with an achieved median of 7.5%). The rate of death for intensive glycemia participants was about 14 people per 1,000 participants treated in the intensive group for one year, compared to about 11 in the standard group. No link was identified by the Data Safety and Monitoring Board between the increased risk of death and any particular medication (including Avandia) or to severe hypoglycemia.

The Steno 2 Study of 160 patients with type 2 diabetes and microalbuminuria showed a 50% reduction in mortality and significant reduction in

microvascular complications five years after ending a 7.8-year multifactorial intervention that achieved A1c of 7.8%, LDL 83 mg/dL, blood pressure (BP) 131/73, compared to a conventional group that achieved A1c 9%, LDL 126 mg/dL and BP 146/78 *[A]*. Results of this study are consistent with the need for reasonable blood sugar control with emphasis on blood pressure and lipid management.

The work group believes that additional sources of data may be available in the near future to provide more evidence for determining optimal glycemic targets.

Until more data is available from ACCORD and other emerging studies, the work group recommends following the suggestion of the director of NHLBI, who states, "Our message to individuals with type 2 diabetes who are at especially high risk for heart disease is to target your A1c level to about 7 percent and not to more intensive levels. No one with diabetes should change their treatment without consulting with their healthcare professional first and we concur with the ADA recommendations that treatment must be individualized." "Especially high risk for heart disease" includes those patients with known heart disease and microalbuminuria, as well as those with two or more risk factors such as obesity, hypertension, hyperlipidemia and smoking.

For patients with long-standing diabetes and cardiovascular risk on insulin or multiple glycemic medications and an A1c under 6.5%, it would be appropriate to make slight medication reductions. For instance, reduce total insulin dose by 10% to 20%, or reduce sulfonylurea dose, particularly if patients have hypoglycemia, or reduce or stop thiazolidinediones (TZDs) if patient has experienced weight gain or edema.

The goal for an individual may be higher or lower depending on the predicted life expectancy, expected clinical benefits and risk of treatment *[R]*. Based on current available evidence, the following factors should be considered when individualizing therapy:

Support for more intensive treatment goals:

- Younger age
- Early disease
- Management with medical nutrition therapy and/or single oral agents

Support for less intensive treatment goals

- Advanced age
- Cardiovascular risk
- Longer duration of diabetes
- Limited life expectancy
- History of severe hypoglycemia
- Hypoglycemia unawareness
- Advanced neurological disease (stroke, dementia)
- Multiple comorbidities
- Polypharmacy concerns

[D]

Glycosylated hemoglobin assays provide an accurate indication of long-term glycemic control. A1c is formed by the continuous non-enzymatic glycosylation of hemoglobin throughout the lifespan of an erythrocyte. This assay yields an accurate measure of time-averaged blood glucose during the previous six to eight weeks.

There are various methodologies (e.g., HbA, A1c, glycated hemoglobin) for this assay. At present, there are no established criteria for use as a diagnostic test. Clinically it can assist in determining duration and severity of hyperglycemia and can help guide treatment.

A1c is not influenced by food intake, physical activity or acute metabolic stress. The test can be done at any time of day and does not require fasting.

Blood sugars should also be used to assess level of glycemic control, in addition to A1c. It is appropriate to determine need for medication changes based on blood sugars whenever this information is available.

Medical centers need to know what the standard is for A1c and glycosylated hemoglobin in their labs and make the appropriate conversions.

Self-Monitoring Blood Glucose (SMBG)

The frequency and timing of self-monitoring blood glucose should be dictated by the particular needs and goals of the individual patient. Patients with type 2 diabetes on insulin typically need to perform self-monitoring blood glucose more frequently than those not using insulin, particularly if using glucose readings to guide mealtime insulin dosing. It is recommended that patients should perform self-monitoring blood glucose three or more times daily for patients using multiple insulin injections *[R]*.

The optimal frequency and timing of self-monitoring blood glucose for patients with type 2 diabetes on oral agent therapy are not known but should be sufficient to facilitate reaching glucose goals. Self-monitoring blood glucose should be performed more frequently when adding or modifying therapy, two-hour postprandial glucose testing is useful in some patients. The role of self-monitoring blood glucose in stable diet-treated patients with type 2 diabetes is not known.

Because the accuracy of self-monitoring blood glucose is instrument and user dependent, it is important for health care providers to evaluate each patient's monitoring technique. In addition, optimal use of self-monitoring blood glucose requires proper interpretation of the data. Patients should be taught how to use the data to adjust food intake, exercise or pharmacological therapy to achieve specific glycemic goals.

Examples of self-monitoring glucose goals, frequency and timing are *[R]*:

- Target preprandial plasma glucose values to a goal of 90 to 130 mg/dL for an A1c goal less than 7%. Target blood sugar readings could be higher or lower depending on individualized A1c goal.
- Average two-hour postprandial plasma glucose values less than 180 mg/dL
- Two-hour postmeal plasma blood glucoses can be helpful for adjusting mealtime medications. The target range for postmeal glucoses is controversial at this time, but a reasonable two-hour postprandial target is within 40 mg/dL higher than the preprandial reading.
- Average bedtime plasma glucose values are less than 120 mg/dL with a goal of 110 to 150 mg/dL
- Bedtime glucose goals vary dependent on the patient's treatment program, risks for hypoglycemia, and time after last meal.
- More than half of the plasma blood glucose readings should fall in the desired goal range.

Start or Intensify Statin Dose

The LDL cholesterol goal for people with diabetes mellitus without coronary artery disease (CAD) is less than 100 mg/dL. The goal with CAD is less than 70 mg/dL.

Intensify statin or lipid-lowering medications to meet LDL cholesterol goals *[A]*.

Recent evidence *[A]* and Adult Treatment Panel III (ATPIII) consensus guidelines *[R]* suggest that statins are beneficial for high-risk patients with a 10-year risk of cardiovascular (CV) event of more than 20% (e.g., coronary heart disease [CHD] equivalency), even with baseline LDL of less than 100 mg/dL.

For patients with type 2 diabetes mellitus, consider use of a statin. *[Conclusion Grade I: See Conclusion Grading Worksheet A -- Annotation #11(Statin Use) [A] in the original guideline document]*.

Use of moderate- to high-dose statins or other LDL cholesterol-lowering medications as needed to achieve an LDL cholesterol value less than 70 mg/dL is recommended for patients with CHD *[A]*.

Three pathways to improve lipids are:

- Medical nutrition therapy
- Increased physical exercise
- Pharmacotherapy

Beneficial effects of statins on cardiovascular risk reduction may, in part, be independent of their effects on lipids. Diabetes is considered a coronary artery disease equivalent. There is an online and a Palm format-downloadable CV risk calculator that is used in assessing 10-year risk of CV disease used in the Adult Treatment Panel III (ATP III) guideline report and this guideline on lipid management *[R]*. The links are:

Online calculator: http://hin.nhlbi.nih.gov/atpiii/calculator.asp?usertype=prof, and

Palm format (downloadable): http://hin.nhlbi.nih.gov/atpiii/riskcalc.htm.

There currently is not evidence for safety and efficacy of combination therapy with statins and other lipid drugs. National Institutes of Health-sponsored randomized controlled studies are currently underway to determine whether adding fibrates or niacin to statin therapy will lower the risk of cardiovascular events for patients with diabetes.

Seventy to seventy-five percent of adult patients with diabetes die of macrovascular disease, specifically coronary, carotid, and/or peripheral vascular disease. Dyslipidemia is a known risk factor for macrovascular disease.

Small density LDL-cholesterol (more atherogenic) particles are increased in type 2 diabetes, and LDL-cholesterol itself may differ in people with diabetes compared with people without diabetes *[R]*. Patients with diabetes develop more atherosclerosis than patients without diabetes with the same quantitative lipoprotein profiles. In individuals with elevated triglycerides, a statin can reduce major vascular events *[C]*.

High triglycerides and low HDL-cholesterol are independent risk factors for cardiovascular disease in the patient with diabetes *[R]*. Individuals with elevated triglycerides have significant cardiovascular risk reduction with the use of fibrates *[A]* or statins [A]. While a number of studies support favorable changes in lipid profiles with niacin alone, randomized controlled trials considering hard cardiovascular outcomes are lacking.

Goals for Blood Pressure Control: BP Less Than 130/80 mm Hg, Emphasis on Systolic BP Control *[R]*

In type 2 diabetes, insulin resistance may cause hypertension by increasing sympathetic activity, renal reabsorption of sodium, or vascular tone.

Uncontrolled hypertension is a major cardiovascular risk factor that also accelerates the progression of diabetic nephropathy *[B]*. When hypertension is identified, it should be aggressively treated to achieve a target blood pressure of less than 130/80 mm Hg. See the Blood Pressure Control algorithm below.

For patients with type 2 diabetes mellitus, the systolic blood pressure goal is less than 130 mm Hg and the diastolic blood pressure goal is less than 80 mm Hg. *[Conclusion Grade II: See Conclusion Grading Worksheet B -- Annotations #11,24, 26 (Goals for BP) in the original guideline document] [A]*.

Aspirin/Antiplatelet Medication Use Unless Contraindicated *[A]*

Patients with type 2 diabetes are at a significantly high risk for development of heart disease *[R]*. For patients with type 2 diabetes mellitus, initiate low-dose aspirin therapy (81 to 325 mg daily) in patients 40 and older unless there is a contraindication to aspirin therapy. *[Conclusion Grade I: See Conclusion Grading Worksheet C -- Annotation #11 (Aspirin Use) in the original guideline document] [A], [B]*.

Higher doses of aspirin thought in the past to be required for clinical effects have been shown to be unnecessary, and are undesirable because of dose-related gastric and hemorrhagic side effects.

If aspirin is contraindicated, consider use of clopidogrel or ticlopidine. For more information, please refer to the NGC summary of the ICSI guideline Stable Coronary Artery Disease and the Antithrombotic Therapy Supplement.

On September 8, 2006, the Food and Drug Administration issued a Safety Information and Adverse Event Report regarding the concomitant use of aspirin and ibuprofen.

Health care professionals should counsel patients about the appropriate timing of ibuprofen dosing if they are taking aspirin for cardioprotective effects.

With occasional use of ibuprofen, there is likely to be minimal risk from any attenuation of the antiplatelet effect of low-dose aspirin, because of the long-lasting effect of aspirin on platelets.

Recommendations include taking immediate-release aspirin (not enteric-coated) 30 minutes or longer prior to taking ibuprofen (400 mg). If ibuprofen is taken first, aspirin should not be taken for at least eight hours after ingestion of ibuprofen.

Enteric-coated aspirin and concomitant use of ibuprofen is unclear. One study showed that 400 mg ibuprofen interfered with the antiplatelet effect of enteric-coated low-dose aspirin at 2, 7 and 12 hours after ingestion *[C]*.

Other non-selective over-the-counter non-steroidal anti-inflammatory drugs (NSAIDs) should be viewed as having the potential to interfere with the anti-platelet effect of low-dose aspirin unless proven otherwise.

For more information, please refer to the information listed on the Food and Drug Administration's Web site for a complete copy of the alert and cited references:
http://www.fda.gov/medwatch/safety/2006/safety06.htm#aspirin.

Goals for Tobacco Use - Smoking Cessation, if Indicated

At a minimum, identify all individuals who use or are exposed to tobacco and provide a brief intervention to help eliminate or at least decrease their use or exposure.

Because effective tobacco dependence treatments are available, every patient who uses tobacco should be offered at least one of these treatments:

- Patients **willing** to try to quit tobacco use should be provided with treatments identified as effective in this guideline.
- Patients **unwilling** to try to quit tobacco use should be provided with a brief intervention designed to increase their motivation to quit.

There is a strong dose-response relation between the intensity of tobacco dependence counseling and its effectiveness. Treatments involving person-to-person contact (via individual, group or proactive telephone counseling) are consistently effective, and their effectiveness increases with treatment intensity, (e.g., minutes of contact) *[R]*.

Brief interventions consist of feedback of screening data designed to increase motivation to change tobacco use behavior, simple advice, health education, goal-setting, practical suggestions, and follow-up, with referral when appropriate. Brief tobacco dependence treatment is effective, and every patient who uses tobacco should be offered at least brief treatment *[R]*.

Tobacco telephone quit lines and proactive telephone counseling increase the odds of abstinence by about 20%. Three types of counseling and behavioral therapies were found to be especially effective and should be used with all patients attempting tobacco cessation:

- Provision of practical counseling (problem-solving/skills training)
- Provision of social support as part of treatment (intratreatment social support)
- Help in securing social support outside of treatment (extratreatment social support)

Numerous effective pharmacotherapies for smoking cessation now exist. Except in the presence of contraindications, these should be used with all patients attempting to quit smoking.

12. **Are Treatment Goals Met?**

Major long-term goals of care in type 2 diabetes are cardiovascular disease prevention (see the related Blood Pressure Control algorithm) and achieving optimal glycemic control (see Glycemic Control algorithm).

Setting initial goals that are achievable, however modest they may be, may encourage patients to take further steps along the way to the more ambitious long-term goals.

Goals and progress towards agreed upon goals should be briefly reviewed at each office visit for diabetes. Adjustment of goals will likely be required over time, and patient involvement in this process can increase levels of patient involvement in care, give patients a greater sense of control of their diabetes, and allow flexibility in management of diabetes during periods of high stress or major life transitions.

13. **Treatment Goals Not Met**

Modify Treatment Based on Appropriate Related Guidelines

- Prevention and Management of Obesity [Adults and Mature Adolescents]
- Hypertension Diagnosis and Treatment
- Lipid Management in Adults
- Major Depression In Adults in Primary Care

See the Glycemic Control and Blood Pressure Control algorithms.

Consider Referral to Diabetes Care Team or Specialists

- **Assess patient adherence**

  Non-adherence with medications can limit the success of therapy and help to explain why a patient is not achieving treatment goals. To screen for non-adherence, clinicians can ask patients open-ended, non-threatening questions at each office visit. The assessment should include probes for factors that can contribute to non-adherence (fear of adverse reactions, misunderstanding of chronic disease treatment, depression, cognitive impairment, complex dosing regimens, or financial constraints).

  - Assess the patient's knowledge of his/her condition and his/her expectations for treatment.
  - Assess the patient's medication administration process.
  - Assess the patient's barriers to adherence.

  Interventions to enhance medication adherence should be directed at risk factors or causes of non-adherence. Interventions may include simplifying the medication regimen, using reminder systems, involving family or caregivers in care, involving multiple disciplines in team care, providing written and verbal medication instructions, setting collaborative goals with patients, and providing education about medications (including potential adverse effects) and about diabetes in general *[R]*.

- **Evaluate for depression**

  There is a substantial increase in the prevalence of depression among people with diabetes as compared to the general adult population *[M]*. The prevalence of depression is two times as likely in people with diabetes and without complications, and depressive symptoms may be found in up to 50% of those who have diabetes with complications. Depression impacts the ability of a person with diabetes to achieve blood glucose control, which in turn impacts the rate of development of diabetes complications *[M]*, *[R]*.

Identification and management of depression is an important aspect of diabetes care. Some clinicians find that either self-administered or professionally administered instruments are useful adjuncts to the clinical interview in the identification of depression. The NGC summary of the ICSI guideline Major Depression in Adults in Primary Care provides more suggestions for the identification and management of depression. Intervention studies have demonstrated that when depression is treated, both quality of life and glycemic control improve. Counseling may be effective, especially among those who are having difficulty adjusting to the diagnosis of diabetes or are having difficulty living with diabetes. Pharmacotherapy for depression is also effective.

- **Diabetes Care Team**

  Assure the patient has an adequate care team.

  Diabetes Educator

  Consultation with a diabetes educator is suggested if the patient is having difficulty adhering to a nutrition, exercise, and medication regimen and the patient is having difficulty adhering to, or accurately completing, blood glucose monitoring, or may need answers to some questions.

  Every primary care physician must develop a relationship with a diabetes education program to provide other options for management. The American Diabetes Association publishes a list of recognized educational programs in each state. These programs may be staffed with endocrinologists or primary care providers plus diabetes educators including dietitians, nurses, and other health care providers who are Certified Diabetes Educators (CDE) or have didactic and experiential expertise in diabetes care and education.

  Endocrinologist/Nephrologist

  Most type 2 diabetes management can be managed by a primary care physician with periodic consultation as needed by an endocrinologist.

  Consultation with a specialist is suggested if persistent proteinuria, worsening microalbuminuria and elevation in serum creatinine or blood urea nitrogen, or hypertension unresponsive to treatment is seen. For additional discussion, see Annotation #33, "Treatment and Referral for Complications, Nephropathy".

  Endocrinologist/Neurologist

  Consultation with a specialist is suggested if neuropathy progresses and becomes disabling.

  Endocrinologist/Cardiologist/Hypertension Specialist

Consultation with a specialist is suggested if blood pressure is refractory to treatment, the patient has marked associated postural hypotension, or symptoms of CAD.

Foot Care Specialist

Consultation with a specialist is suggested if the patient is unable to care properly for his/her own feet, needs prescriptive footwear, and/or more serious problems such as foot deformities (e.g., Charcot deformity), infected lesions, and ulcers, deformed nails, or thick calluses are present.

Glycemic Control Algorithm Annotations

15. **Glycemic Control Algorithm**

    Medical nutrition therapy may be all that is required to treat diabetes, especially for the patient with early mild symptomatic disease. Medical nutrition therapy should be maintained throughout the course of the disease, even as pharmacologic agents are used. Oral agent medications are generally used if medical nutrition therapy alone does not succeed in obtaining patients' goals within a reasonable time frame, usually no longer than two to three months. Metformin plus lifestyle treatment is also a reasonable initial therapy at the time of diagnosis, given the low risk of hypoglycemia and benefits of metformin shown in both prediabetes and diabetes *[R]*.

    At the time of diagnosis, if patients have severe symptomatic disease, insulin should be initiated. With appropriate educational support and care, the risks of insulin may not differ from many oral agents. In some circumstances when glucose intolerance is significant and the patient is unwilling to consider insulin or it is not felt to be appropriate, the initiation of combinations of oral agents can be appropriate. Insulin is indicated when there is a failure to achieve treatment goals with oral agents.

    It is important to remember that patients can move both ways on the Glycemic Control algorithm, (e.g., they can move off of specific pharmacologic therapies as lifestyle changes are made that improve glycemic control). Diabetes is a progressive disease, however, and the use of pharmacologic agents will likely become necessary in the majority of patients, even if they are able to follow through with nutrition and physical activity recommendations *[A]*.

16. **Pharmacologic Agent(s) - Which is Best?**

    Key Points:

    - Age and weight of the patient, as well as presence of renal dysfunction, cardiopulmonary comorbidities, and hepatic disease must be considered when choosing pharmacologic agents.

Annotations #17 and #19 will address specific medications and the treatment of hyperglycemia. Only general guidelines can be given when deciding about which pharmacologic agent will be best for a specific patient. While each patient presents with unique circumstances, the work group offers the following clinical circumstances to consider.

Age of Patient

It is important to recognize that risks of medications are often increased with advancing age, but this does not justify the withholding of medications that may reduce the symptoms of polyuria, nocturia, and frequent visits to the bathroom that may place the patient at risk of hip fracture or falls.

With age, decline in renal function is often not reflected in a measurable change in serum creatinine because of an accompanying decline in muscle mass. Because of this, metformin should be used with caution in elderly patients (over age 80).

Decline in ventricular function and risks for volume overload can be occult in the elderly and may become clinically apparent with the use of thiazolidinediones.

In select circumstances, because of the risks of hypoglycemia, variable diet habits and renal clearance and function, it may be safer to consider initial low dose short-acting sulfonylurea (e.g., glipizide or repaglinide/nateglinide when a meal is eaten).

Weight of the Patient

Type 2 diabetes is often associated with insulin resistance and weight gain. Metformin, acarbose, exenatide, sitagliptin, and human amylin are more often associated with weight loss or weight maintenance. Due to its weight benefits as well as general tolerability, lower cost, and proven benefits in the United Kingdom Prospective Diabetes Study Group, metformin is recommended for most diabetes patients with type 2 diabetes unless contraindicated. Insulin and thiazolidinediones may be associated with weight gain *[A]*.

Renal Dysfunction

Renal dysfunction increases the risk for hypoglycemia in particular with the use of oral hypoglycemic agents.

Metformin and alpha glucosidase inhibitors should not be used.

Thiazolidinediones may be considered, but the potential risks of fluid retention and increased risk of cardiac events need to be considered.

Short-acting oral agents glipizide, glimepiride (in which serum levels have been noted to decrease in mild renal failure), repaglinide, or nateglinide may be preferred if an oral agent is felt to be necessary in the face of renal dysfunction.

Insulin may be the safest when serum creatinine is greater than 1.8 mg or creatinine clearance is less than 60 mL/min.

Cardiopulmonary Comorbidities

Metformin is contraindicated in patients with heart failure treated with medication. Metformin should be used with caution in patients with conditions that predispose them to risk of hypoxia such as chronic obstructive pulmonary disease (COPD) or obstructive sleep apnea.

Patients started on thiazolidinediones should be instructed to report signs of lower extremity swelling, rapid weight gain, and shortness of breath. Risk of thiazolidinediones needs to be discussed and documented before using in patients with cardiovascular risks. Please see the thiazolidinediones warning for more information.

Short acting sulfonylurea (e.g., glipizide), repaglinide/nateglinide, and the cautious use of long-acting sulfonylurea agents, or insulin may be safest.

Hepatic Disease

Hepatic disease or insufficiency increases the risks of lactic acidosis and hypoglycemia and influences the metabolism of many oral agent medications.

Metformin and thiazolidinediones should not be used if alanine aminotransferase (ALT) is 2.5 to 3 times normal upper limits.

First generation sulfonylureas, glipizide, and glyburide have some component of hepatic metabolism and should be used with caution because of the risks of hypoglycemia. Insulin would be considered safest.

17. **Prescribe Insulin Therapy**
    - Insulin programs should be individualized based on the patient's lifestyle, treatment goals, and self-monitoring blood glucose. Many patients can be taught to interpret self-monitoring blood glucose results and adjust insulin doses *[R]*.
    - Human insulin is now the only available insulin in the United States.
    - Total dose ranges from 5 units/day to several hundred units/day.
    - Average insulin doses are 0.6 to 0.8 units/kg of body weight per day.
    - Obese patients often require doses equal to or exceeding 1.2 units/kg.
    - Meal times and snacks must be consistent. Synchronize insulin with food intake patterns.
    - A table showing the time course of action of insulin preparations is presented in the original guideline document. This table summarizes the typical time course of action of various insulin preparations. These values are highly variable among individuals. Even in a given patient, these values vary depending on the site and depth of injection, skin temperature and exercise.
    - No pronounced peak: small amounts of insulin are slowly released resulting in a relatively constant concentration/time profile over 24 hours.

- Rapid-acting insulin should not be taken more than 15 minutes before meals in contrast to regular insulin which should ideally be taken at least 30 minutes before a meal to better match the insulin peak action with post-meal hyperglycemia.
- Patients who are testing their blood glucose before meals and adjusting insulin doses to match meals may find rapid-acting insulin to be more effective although generally studies have not shown an improvement in A1c when compared to regular insulin taken according to package insert (30 to 45 minutes preprandial).
- Effective use of rapid-acting insulin usually requires the addition of basal intermediate or long-acting insulin.
- Glargine should not be mixed with other insulins, diluted with other solutions, or given intravenously.
- Glargine insulin is most often administered once a day, either at bedtime or in the morning.
- Insulin pump therapy may be helpful for patients who are interested in more intensified management of blood sugars and want more flexibility, or if pregnancy is desired. Candidates for pump therapy should be evaluated by an endocrinologist or diabetes specialist to assess patient understanding, self-care knowledge including medical nutrition therapy, responsibility, and commitment. Insulin pump therapy is more commonly used in type 1 patients, but is also being used by some type 2 patients.
- Please note the work group left the brand names for Humalog® and Novolog® in the table. The generic mix is as follows:
    - Humalog mix: lispro protamine suspension/lispro injection
    - Novolog mix: aspart protamine suspension/aspart injection

19. **Prescribe Non-Insulin Agents**

Please consult the manufacturer's product labeling insert for full prescribing information.

If not contraindicated, metformin is the preferred initial oral agent for type 2 diabetes due to low cost, low risk of hypoglycemia and side effects, and lack of associated weight gain. If metformin is contraindicated, sulfonylureas and glitazones are acceptable secondary choices for oral agents. Sulfonylureas have the advantage of being relatively inexpensive, and glitazones are contraindicated in congestive heart failure *[R]*.

See the original guideline document for details on dosage, cost, efficacy and safety of the following non-insulin agents:

- Metformin (regular and extended-release)
- Second-generation sulfonylureas (regular and extended release glipizide, regular and micronized glyburide, glimepiride)
- Alpha glucosidase inhibitors (acarbose and miglitol)
- Dipeptidyl peptidase-4 (DDP-4) inhibitor (sitagliptin)
- Meglitinides (short-acting secretagogues) (repaglinide and nateglinide)
- Glucagon-like peptide 1 (GLP-1) agonist (exenatide injection)
- Synthetic analog of human amylin (pramlintide acetate injection)
- Thiazolidinediones (TZD) (pioglitazone, rosiglitazone)

- Combination products (TZD + metformin, sulfonylurea + metformin, TZD + sulfonylureas, DDP-4 inhibitor + metformin)

22. **Intensify Therapy**

    If treatment goals are not met on oral agents, or if oral agents are contraindicated, then it is necessary to begin insulin either alone or as an adjunct to oral therapy. There are many regimens that have been studied and are efficacious *[A]*, *[R]*. The following are some commonly used regimens.

    Insulin as an adjunct to oral therapy:

    - A bedtime dose of NPH, or glargine insulin, is added to metformin or thiazolidinediones. The starting dose of basal insulin is often 0.1 units/kg, based on current body weight. If patient is also on a sulfonylurea, it may be discontinued when insulin is added.
    - A bedtime dose of insulin (as above) is added to sulfonylurea. The dose of the sulfonylurea may be reduced by approximately 50% when insulin is added.

    Insulin alone:

    - Twice-daily insulin regimen is established with progression to increased frequency of insulin administration as necessary to achieve treatment goals or to add flexibility to a patient's meal and activity schedules. Multiple dose insulin with rapid-acting and basal insulin therapy may offer patients with active lifestyles the greatest flexibility.

    Oral agents as an adjunct to insulin therapy:

    - Metformin may be helpful as an adjunct for patients who require large doses of insulin (e.g., greater than 100 units/day).

Blood Pressure Control Algorithm Annotations

23. **Blood Pressure Control Algorithm**

    Control of BP is at least as important as glycemic control for people with type 2 diabetes in reducing the risk of complications *[A]*.

24. **Is Systolic Blood Pressure Greater Than or Equal to 130 mm Hg?**

    For patients with Type 2 diabetes mellitus, the systolic BP goal is less than 130 mm Hg and the diastolic BP goal is less than 80 mm Hg. *[Conclusion Grade II: See Conclusion Grading Worksheet B -- Annotation #11, 24, 26 (Goals for BP) in the original guideline document] [A]*.

    A report from the UK Prospective Diabetes Study Group showed an inverse relationship between systolic blood pressure and the aggregate end point for any complication related to diabetes *[R]*. The lowest risk occurred at a systolic BP below 120 mmHg.

The goal for patients with renal insufficiency and urinary protein excretion greater than 1 to 2 g/day should be less than 120/75 mm Hg *[R]*.

25. **Treat Systolic Blood Pressure to less than 130 mm Hg. While Angiotensin-Converting Enzyme (ACE) Inhibitors and Angiotensin II Receptor Blockers (ARBs) are Preferred First Line Therapy, Two or More Agents (to Include Thiazide Diuretics) May Be Required**

    Non-pharmacologic and pharmacologic methods are recommended at blood pressures greater than or equal to 130/80 mmHg. The initial focus of treatment should be the systolic blood pressure.

    For patients with type 2 diabetes mellitus, ACE inhibitors or ARBs can reduce progression of micro- and macrovascular complications. *[Conclusion Grade I: See Conclusion Grading Worksheet D -- Annotations #25, 33 (Treatment with ACE Inhibitors or ARBs) in the original guideline document] [A]*.

    While ACE inhibitors and ARBs are preferred first-line therapy, two or more agents (to include thiazide diuretics) may be required. For patients with type 2 diabetes mellitus, thiazide diuretics in the treatment of hypertension can reduce cardiovascular events, particularly heart failure. *[Conclusion Grade I: See Conclusion Grading Worksheet E -- Annotations #25, 33 (Thiazide Diuretics) in the original guideline document] [A], [B]*. The possible advantages to ACE inhibitors include renal protection, decreased insulin resistance, lack of adverse effect on lipids, and decreased cardiovascular risk reduction.

    Treatment of isolated systolic hypertension, as well as combined systolic and diastolic hypertension, in both young and elderly people protects against major cardiovascular diseases. Drug treatment should be initiated if systolic BP is greater than or equal to 130 mm Hg *[R]*.

    Thiazide diuretics used in the treatment of hypertension can reduce cardiovascular events, especially heart failure, for patients with type 2 diabetes *[A]*, *[D]*, *[R]*.

26. **Is Diastolic Blood Pressure Less Than 80 mm Hg?**

    For patients with type 2 diabetes mellitus, the systolic blood pressure goal is less than 130 mm Hg and the diastolic blood pressure goal is less than 80 mm Hg. *[Conclusion Grade II: See Conclusion Grading Worksheet B -- Annotations #11, 24, 26 (Goals for BP) in the original guideline document] [A]*.

    The Hypertension Optimal Treatment (HOT) trial provides evidence that a target diastolic blood pressure less than 80 mm Hg has a cardioprotective effect in people with diabetes. This study reported that in the diabetic subgroup (n=1,501) major cardiovascular events were reduced by greater than 51% (p=0.005) in those randomized to a diastolic BP goal of less than 80 mm Hg compared to less than 90 mm Hg. The HOT study has been criticized by some because this was a post hoc analysis of a subgroup of

patients in the study and the number of events is relatively small. Nevertheless, results are consistent with UK Prospective Diabetes Study. UK Prospective Diabetes Study achieved an average diastolic blood pressure of 82 in the tightly controlled group (vs. 87 mm Hg in the less tightly controlled group). The more tightly controlled group had diabetes related end points reduced by 24% (p=0.005) and death by 32% (p=.019) *[A]*.

Treat Diastolic Blood Pressure to Less Than 80 mm Hg

Combinations of medications are often required to achieve goals. Thirty percent of patients in the tight blood pressure arm of the United Kingdom Prospective Diabetes Study with goal less than 150/85 mm Hg required 3 or more antihypertensive medications to achieve the mean 144/82 mm Hg. Findings from the ALLHAT study suggest that thiazide diuretics be considered as part of a multi-drug regimen *[A]*, *[M]*.

Ongoing Management Algorithm Annotations

30. **Ongoing Management and Follow-Up of People with Diabetes**

In studies of general population groups, coronary artery disease deaths have been substantially reduced by the treatment of hypertension, hypercholesterolemia and smoking. Lipid treatment has also been shown to be of benefit in diabetes. Therefore, risk factor reduction is prudent for patients with diabetes. Data also supports the daily use of aspirin as a method to reduce cardiovascular events in patients with diabetes. See Annotation #11, "Standardized Treatment Goals, Start or Intensify Statin Dose" and the Blood Pressure Control algorithm *[A]*, *[R]*.

- Frequency of visits depends on blood glucose control, changes in the treatment regimen, and presence of complications of diabetes or other medical conditions.
- Patients starting or having a major change in their treatment program (such as initiating insulin therapy) may need to be in contact with their care provider as often as daily until glucose control is achieved, the risk of hypoglycemia is low, and the patient is competent to conduct the treatment program.
- Contact with the patient after a major modification of the treatment plan (such as introducing a new medication) should not be delayed greater than 1 week.
- Regular visits should be scheduled for insulin-treated patients at least quarterly and for other patients at least semiannually. More frequent visits may be necessary if treatment goals are not achieved.
- Cardiovascular disease is the primary cause of morbidity and mortality in people with type 2 diabetes. The risk of coronary artery disease is approximately doubled in men and quadrupled in women with diabetes.
- At each encounter, ask if the patient has experienced symptoms of hypoglycemia or low blood sugars and educate the patient on appropriate recognition, prevention, and management.
- If the patient has a history of severe hypoglycemia (assistance of another person was needed to treat a low sugar) or has developed

hypoglycemia unawareness, evaluate the treatment goals for appropriate safety.

31. **Maintain Treatment Goals**
    - Nutrition/physical activity: Work with individual patients regularly to set realistic goals.
    - Monitor A1c every 3 to 6 months. In insulin treated patients and non-insulin-treated patients with poor metabolic control, quarterly A1c may assist management
        - Review blood sugars at all patient encounters. Reinforce blood sugar targets with patients and educate regarding hypoglycemia.
    - Monitor lipid profile yearly (cholesterol, triglycerides, HDL cholesterol, and LDL). Treat to achieve recommended goals. (See Annotation #11, "Standardize Treatment goals, Start or Intensify Statin Dose"). If lipid goals are consistently met, patient is in metabolic control, has stable clinical conditions, and has not had a change in medication, an annual lipid profile is not mandatory.

      Diabetes is a major risk factor for coronary artery disease, and many patients with diabetes also have lipid disorders *[R]*. Thus, control of dyslipidemia in diabetes is important because evidence shows that correcting lipid disorders reduces the rate of coronary artery disease events.

    - Monitor BP each visit and control hypertension to recommended levels. See the Blood Pressure Control algorithm.
    - Ask about aspirin use and recommend aspirin use in patients age 40 and over unless contraindicated *[R]*.
    - Ask about alcohol and tobacco use and assist with cessation if indicated.

32. **Annual Assessment of Complications**

    Targeted Annual History and Physical Exam

    - The history should assess *[R]*:
        - Results of self monitoring blood glucose; validate results at least once a year (i.e., check patient's glucose meter against an office random capillary glucose)
        - Adjustments by the patient of the therapeutic regimen
        - Frequency, causes, and severity of both hyperglycemia and hypoglycemia
        - Problems with adherence to therapeutic regimen
        - Symptoms suggesting development or progression of the complications of diabetes
        - Current prescribed medications, over-the-counter medications, dietary supplements and alternative therapies
        - Documentation of eye care specialist exam results
        - Alcohol/drug use patterns
        - Lab assessment of liver function and/or creatinine to assess ongoing acceptability of medication usage

- The targeted physical exam should assess:
    - Weight, body mass index (BMI)
    - Blood pressure
    - Cardiovascular - evaluation of preexisting problems
    - Feet (nails, web spaces, calluses, ulcers, structural deformities, protective sensation and shoes)

Specialist Dilated Eye Exam

A dilated eye examination for diabetic eye disease performed by an ophthalmologist or optometrist is recommended annually for patients with type 2 diabetes mellitus *[R]*. Less frequent exams (every two to three years) may be considered in the setting of a normal eye exam.

Renal Assessment

Urinary albumin excretion should be tested annually by a microalbuminuria method. There are racial/ethnic variability with regard to the prevalence of ESRD, with Native Americans, Latinos (especially Mexican Americans), and African Americans having higher rates than non-Hispanic whites with type 2 diabetes *[R]*. If albuminuria is above normal, serum creatinine should be measured. Screening for microalbuminuria can be performed by three methods *[B]*, *[R]*:

- Measurement of the albumin-to-creatinine ratio in a random, spot collection. This is easiest to perform, generally accurate and therefore is the preferred screening method.
- 24-hour collection with creatinine, allowing for simultaneous measurement of creatinine clearance
- Timed (four-hour or overnight) collection

Some factors can artificially increase the levels of albumin in the urine and should be avoided at the time of the urine collection; these factors include blood in the urine, prolonged heavy exercise, fever, congestive heart failure, uncontrolled diabetes, severe hypertension, urinary tract infection, and vaginal fluid contamination of specimen.

If the dipstick or urine analysis test is negative for protein, then a more sensitive early screening test is indicated. A qualitative urinary microalbumin screen can be used to detect urinary microalbumin. If the qualitative test is positive, a quantitative test must be performed.

A microalbumin screening test should be done each year on patients with type 2 diabetes. If positive (exceeds 30 mg/g), it should be repeated twice in the next three months.

If two out of three of these screening microalbuminuria tests are positive, the individual has microalbuminuria and interventions should be considered. A negative finding should be followed annually; a positive finding should be followed periodically to see if the interventions are effective in diminishing the albuminuria *[R]*.

See Appendix B, "Treatment of Diabetic Nephropathy," in the original guideline document.

Comprehensive Foot Exam with Risk Assessment

Patients with one or more risk factors for foot complications should be educated about their risk factors and appropriate measures taken to avoid complications. Measures may include self-management education, more intensive follow-up, and/or referral to appropriate specialist *[R]*.

Risk factors for foot complications include:

- Loss of protective sensation. Protective sensation can be assessed using either a 5.07 Semmes-Weinstein monofilament for light touch or by testing vibration using a 128-Hz tuning fork at the dorsum of the interphalangeal joint of the great toe, or both. Patients with reduced or absent sensation with either of these tests should be educated about their risk and the need for proper foot care to prevent foot complications. See Appendix A, "Using a Semmes-Weinstein Monofilament to Screen the Diabetic Foot for Peripheral Sensory Neuropathy" in the original guideline document)
- Peripheral vascular disease (absent pedal pulse, history of claudication, or ischemic skin changes)
- Structural deformities (bunion, hammertoes, Charcot deformity, limited joint mobility, or prior amputation)
- Skin disorders (nail deformity, callus, fissure, tinea, or ulceration)
- Footwear (excessively worn, ill fitting, or inappropriate shoes)

Cardiovascular and Cerebrovascular Complication Assessment

- History of cardiovascular symptoms such as chest pain, vascular claudication, transient ischemic attack (TIA)
- Cardiac and carotid exams
- Evaluate cardiovascular status before advising increased intensity of exercise *[R]*

Special Considerations

- Influenza vaccine every year
- Pneumococcal vaccine - consider repeating the immunization for those at risk of losing immunity after five years including:
    - Nephrotic syndrome
    - Chronic renal disease
    - Other immunocompromised states
- There is evidence that ACE inhibitors and ARBs are beneficial in reducing cardiovascular morbidity and mortality in acute MI, congestive heart failure, and type 2 diabetes patients at high risk for cardiovascular disease; they are also beneficial in improving renal outcomes in diabetes. Results of the HOPE (Heart Outcomes Prevention Evaluation) study strongly support the use of ACE inhibitors for patients with diabetes who are at high risk for cardiovascular disease. In the Second Australian National Blood Pressure Study

(ANBP2), the use of ACE inhibitors in older patients was associated with better cardiovascular outcomes despite similar reductions in blood pressure from diuretics. Confirming studies would be helpful to strengthen this recommendation or to generalize recommendations to all patients with diabetes *[A]*.
- Vitamin E has no apparent effect on cardiovascular outcomes *[A]*.
- Osteoporosis: Type 2 diabetes does not appear to be a risk factor for decreased bone mineral density; nonetheless, some studies have found an increased fracture risk for people with type 2 diabetes *[B]*. Hypoglycemic episodes, decreased visual acuity secondary to retinopathy, and altered balance and postural control secondary to peripheral and autonomic neuropathy can all increase the risk of falls and fracture.

  In the absence of diabetes specific osteoporosis screening guidelines, it is reasonable to follow general osteoporosis screening recommendations for people with diabetes.

See the NGC summary of the ICSI guideline Diagnosis and Treatment of Osteoporosis for more information.

33. **Treatment and Referral for Complications**

Nephropathy

In type 2 diabetes, albuminuria may be present at the time of diagnosis in about 10 percent of patients, and another 10 percent later develop it. Progression to renal failure is less certain in type 2 patients than in type 1 patients, and appears to be modulated by genetic and other factors.

Patients with clinical nephropathy almost always have retinopathy and coronary artery disease.

Numerous interventions are appropriate at different stages of renal function in order to prevent or slow the progression of renal disease and associated cardiovascular disease and include *[R]*:

- Glucose Control - Improved glucose control at any stage of renal function reduces renal disease progression. See the Glycemic Control algorithm.
- For patients with type 2 diabetes mellitus, ACE inhibitors or ARBs can reduce progression of micro- and macrovascular complications. *[Conclusion Grade I: See Conclusion Grading Worksheet D -- Annotations #25, 33 (Treatment with ACE inhibitors or ARBs) in the original guideline document] [A]*. These agents appear effective even in normotensive microalbuminuric individuals. This class of drugs must not be used in pregnancy. Within one week of initiation, check for elevations in potassium and creatinine levels and monitor for cough.
- Hypertension Control - Although ACE inhibitors and ARBs seem to have special renal protective properties beyond their antihypertensive effect, any effort to optimize blood pressure will help the kidneys. When significant microalbumin or overt nephropathy is present, there

may be a tendency to retain sodium. In this case, a loop diuretic added to the antihypertensive regimen is often helpful. A few studies show certain calcium channel blockers reduce microalbuminuria. A goal BP of 130/80 is recommended *[R]*. See the Blood Pressure Control algorithm.

For patients with type 2 diabetes, thiazide diuretics in the treatment of hypertension can reduce cardiovascular events, particularly heart failure. *[Conclusion Grade I: See Conclusion Grading Worksheet E – Annotations #25, 33 (Thiazide Diuretics) in the original guideline document [A], [B].*

In ALLHAT, chlorthalidone, at doses of 12.5 to 25 mg daily, was superior to other treatments at reducing cardiovascular events in both diabetic and non-diabetic patients.

- Cardiovascular Risk Factor Intervention - Dyslipidemia is often present with microalbuminuria and should be treated aggressively. Dyslipidemia may be an independent risk factor for progression of renal disease. Smoking is associated with the onset and progression of microalbuminuria.
- Restriction of dietary protein has been shown to slow progression of overt nephropathy (macroalbuminuria), and there may be some benefit in dietary protein reduction in microalbuminuric patients. In these circumstances, protein intake should be reduced to the adult recommended daily allowance of 0.8 to 1.0 g/kg body weight per day with microalbuminuria present, and 0.8 g/kg body weight per day with macroalbuminuria present *[R]*.

  Treatment for microalbuminuria includes aggressive blood pressure control, glycemic control, ACE inhibitor or ARB use, and aggressive cardiovascular risk factor screening and management. Strongly consider referral to nephrology any patients with a creatinine greater than 1.5 mg or nephrotic range proteinuria (greater than 3 g/24 hr). Nephrology interventions often include early patient education as renal disease progresses, review and reinforcement of the medical regimen, and preservation of arm veins for future vascular access. Patients with a creatinine clearance of less than 30 mL/min should be referred to nephrology for discussions of future options and to enhance the ability to receive a future transplant. These patients also have significant enough renal impairment that they also benefit from more intensive nutritional interventions and proper management of anemia and bone disease *[A]*, *[B]*, *[R]*. See the Blood Pressure Control algorithm.

Neuropathy: Peripheral neuropathy is difficult to prevent and treat. Most patients with type 2 diabetes and peripheral neuropathy have few symptoms but are found on examination to have diminished reflexes and sensation. Sometimes neuropathy can be very painful, especially at night, with "pins-and-needles" numbness and tingling in a stocking-and-glove distribution. Absence of reflexes or decreased thermal, vibratory, proprioceptive or pain sensation may be noted on examination and confirm the diagnosis. Good glycemic control should be the first control to symptomatic neuropathy.

Treatment with amitriptyline, nortriptyline, or trazodone in doses beginning at 25 mg at night and increasing to 75 mg may help some patients. Topical treatment with capsaicin, 0.025% cream three to four times per day, has also shown benefit. Carbamazepine, duloxetine, and gabapentin may also improve neuropathic pain. These medications may provide symptomatic relief, but they do not improve the neuropathy *[R]*.

Retinopathy: Prevalence of retinopathy is related to the duration of diabetes mellitus. After 20 years of type 2 diabetes mellitus, more than 60% of patients have some degree of retinopathy *[R]*. Diabetic retinopathy is estimated to be the most frequent cause of new cases of blindness among adults ages 20 to 74 years.

Up to 21% of patients with type 2 diabetes mellitus are found to have retinopathy at the time of diagnosis of diabetes mellitus *[R]*. Generally retinopathy progresses from mild background abnormalities to preproliferative retinopathy to proliferative retinopathy.

Poor glucose control is associated with progression of retinopathy. High blood pressure is a risk factor for the development of macular edema and is associated with the development of proliferative retinopathy *[R]*.

Screening for diabetic retinopathy saves vision at a relatively low cost. In fact, screening costs may be less than the costs of disability payments for those who become blind. Laser photocoagulation surgery is effective in preventing visual loss in diabetic retinopathy.

Studies have shown that retinal examinations by physicians who are not eye care specialists are not reliable in detecting retinopathy *[A]*, *[C]*, *[R]*.

Treatment includes glycemic and blood pressure control. Periodic screening and dilated eye exams by an eye specialist and early treatment of diabetic retinopathy prevents visual loss *[R]*. See the Glycemic Control and Blood Pressure Control algorithms.

Cardiovascular and Cerebrovascular disease: Treatment includes control of cardiovascular risk factors (hypertension, hyperlipidemia, and smoking cessation) and aspirin use. Consider referring patients with known CAD to cardiology and patients with known carotid disease to surgery.

Heart failure is also common in patients with diabetes. Caution should be used when prescribing spironolactone and eplerenone to people with diabetes, especially in combination with ACE inhibitors. Close monitoring of potassium and renal function is necessary. For patients with type 2 diabetes mellitus, thiazide diuretics in the treatment of hypertension can reduce cardiovascular events, particularly heart failure. *[Conclusion Grade I: See Conclusion Grading Worksheet F -- Annotations #25, 33 (Thiazide Diuretics) in the original guideline document] [A]*.

Patients with type 2 diabetes have twice the average risk of suffering a stroke *[R]*. It is unclear whether good glycemic control reduces this risk. However,

treatment of hypertension, smoking, and hyperlipidemia reduces the risk of stroke in most persons. See Annotation #11, "Standardized Treatment Goals" and the Blood Pressure Control algorithm.

Peripheral Vascular Disease: Peripheral arterial disease is commonly associated with diabetes *[R]*. As many as 36% of patients with diabetes have lower-extremity peripheral arterial disease based on lower-extremity blood pressure readings. However, a typical history of intermittent claudication or an absent peripheral pulse is less commonly noted.

Peripheral vascular disease in combination with peripheral neuropathy places patient with diabetes at increased risk for nontraumatic amputations of the lower extremity. Peripheral vascular disease may be slowed by smoking cessation and treatment of hypertension and dyslipidemia. (See Annotation #11, "Standardized Treatment Goals, Start or Intensify Statin Dose" and the Blood Pressure Control algorithm).

Aggressive daily foot care, inspection of the feet at every office visit, early treatment of foot infections, treatment of callus, use of moisturizing lotion, and proper footwear may forestall problems, including amputation. Vascular surgery may also prevent amputation in some patients with established severe peripheral vascular disease *[R]*.

Proper high-risk foot management is necessary to prevent ulceration and amputation. Consider referral of patients with claudication and/or absent pedal pulses to surgery. See the Glycemic Control and Blood Pressure Control algorithms.

Definitions:

Conclusion Grades:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results of different studies or because of serious doubts about generalizability, bias, research design flaws, or

adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

Classes of Research Reports:

A. Primary Reports of New Data Collection:

Class A:

- Randomized, controlled trial

Class B:

- Cohort study

Class C:

- Nonrandomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D:

- Cross-sectional study
- Case series
- Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports:

Class M:

- Meta-analysis
- Systematic review
- Decision analysis
- Cost-effectiveness analysis

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

- Medical opinion

CLINICAL ALGORITHM(S)

Four detailed and annotated clinical algorithms are provided for:

- Management of Type 2 Diabetes Mellitus in Adults
- Glycemic Control
- Blood Pressure Control
- Ongoing Management

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is classified for selected recommendations (see "Major Recommendations").

In addition, key conclusions contained in the Work Group's algorithms are supported by a grading worksheet that summarizes the important studies pertaining to the conclusion. The type and quality of the evidence supporting these key recommendations (i.e., goal for glycemic control; goal for LDL level; goals for blood pressure, aspirin use, and treatment with angiotensin converting enzyme [ACE] inhibitors or angiotensin II receptor blockers [ARBs]) is graded for each study.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Effective medical management of "prediabetes" (impaired fasting glucose or impaired glucose tolerance) and type 2 diabetes mellitus through a comprehensive approach that includes nutrition therapy, physical activity recommendations, pharmacologic therapy, self-management, as well as prevention and diagnosis of diabetes-associated complications and risk factors

POTENTIAL HARMS

- With *second generation sulfonylureas*, there are rare cross-sensitivities for patients with sulfa allergies. These agents should be used with caution in patients with hepatic or renal failure. Hypoglycemia risk increases with impaired renal function. Glyburide has the highest rate of hypoglycemia of all the sulphonylureas.
- *Metformin* may have unpleasant side effects such as metallic taste, diarrhea, nausea, and anorexia. These may be transient. Use with caution in elderly. The use of metformin in pregnancy or lactation is not recommended.
- Abdominal cramping, flatulence, and diarrhea are common side effects of *alpha glucosidase inhibitors*. Tolerance may develop. Absorbed drug metabolites of acarbose may rarely cause elevated transaminase levels.
- *Dipeptidyl Peptidase-4 (DPP-4) inhibitor (sitagliptin)* is associated with nasopharyngitis, upper respiratory tract infections, and headache. Dosage adjustment is recommended in patients with moderate or severe renal

insufficiency and in patients with end-stage renal disease. Assessment of renal function is recommended prior to initiating sitagliptin and periodically thereafter. When used with a sulfonylurea, a lower dose of sulfonylurea may be required to reduce the risk of hypoglycemia.

- *Thiazolidinediones*, alone or in combination with other antidiabetic agents including insulin, can cause fluid retention, which may lead to heart failure. Side effects may include moderate weight gain, edema, and mild anemia, all due, at least in part, to fluid retention. The use of agents is not recommended in pregnancy and lactation. Both low-density lipoprotein and high-density lipoprotein cholesterol concentrations may increase slightly. Administration of gemfibrozil increases plasma levels of rosiglitazone. Decreases in the dose of rosiglitazone may be needed when gemfibrozil is added. Rosiglitazone may increase cardiovascular events and is not recommended as an initial treatment. Meta-analyses showed rosiglitazone may be associated with an increase in the risk of myocardial infarction and death from cardiovascular causes. Macular edema has been reported in postmarketing experience in some diabetic patients who were taking thiazolidinedione. The risk of fracture should be considered in the care of patients, especially female patients, treated with thiazolidinedione.
- Hypoglycemia is the major side effect of *meglitinides* (short-acting secretagogues). Avoid concomitant use of gemfibrozil and repaglinide.
- Caution should be used when prescribing *spironolactone* and *eplerenone* to people with diabetes, especially in combination with angiotensin-converting enzyme (ACE) inhibitors.
- Weight loss is associated with *glucagon-like peptide 1 (GLP-1) agonist-exenatide injection*, especially when used concomitantly with metformin. It is not recommended for use in patients with end-stage renal disease or severe renal impairment (creatinine clearance <30 mL/min), as well as severe gastrointestinal disease because its use is commonly associated with gastrointestinal adverse effects, including nausea, vomiting, and diarrhea. Caution should be used in patients receiving oral medications that require rapid gastrointestinal absorption. For oral medications that are dependent on threshold concentrations for efficacy, such as contraceptives and antibiotics, patients should be advised to take those drugs at least 1 hour before exenatide injection.
- Use of *synthetic analog of human Amylin - pramlintide acetate injection* is commonly associated with gastrointestinal adverse effects, including nausea, anorexia, and vomiting. When the rapid onset of a concomitant orally administered agent is a critical determination of effectiveness, the agent should be administered at least 1 hour prior to 2 hours after pramlintide injection. This product and insulin should always be administered as separate injections and never be mixed. Mixing will alter the pharmacokinetics parameters of pramlintide. Co-administration of pramlintide with insulin therapy increases the risk of insulin-induced severe hypoglycemia.
- On September 8, 2006, the Food and Drug Administration issued a Safety Information and Adverse Event Report regarding the concomitant use of aspirin and ibuprofen. Recommendations include taking immediate-release aspirin (not enteric-coated) 30 minutes or longer prior to taking ibuprofen (400 mg). If ibuprofen is taken first, aspirin should not be taken for at least eight hours after ingestion of ibuprofen. Enteric-coated aspirin and concomitant use of ibuprofen is unclear. One study showed that 400 mg ibuprofen interfered with the antiplatelet effect of enteric-coated low-dose aspirin at 2.7 and 12 hours after ingestion. Other non-selective over-the-

counter (OTC) non-steroidal anti-inflammatory drugs (NSAIDs) should be viewed as having the potential to interfere with the antiplatelet effect of low-dose aspirin unless proven otherwise.

CONTRAINDICATIONS

CONTRAINDICATIONS

Sulfonylureas

- Diabetic ketoacidosis
- Hypersensitivity to sulphonylureas

Metformin

- Hypersensitivity, acute or chronic metabolic acidosis (including diabetic ketoacidosis)
- Renal disease (creatinine $\geq$1.5 mg/dL in men, $\geq$1.4 mg/dL in women)
- Chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF treated with medication), severe hepatic disease, or alcoholism

Alpha Glucosidase Inhibitors

- Serum creatinine levels greater than 2 mg/dL
- Abnormal baseline liver function tests
- Inflammatory bowel disease
- Hypersensitivity

Thiazolidinediones

- Hypersensitivity
- Moderate to severe heart failure (New York Heart Association [NYHA] Class III and IV cardiac status)

Angiotensin-Converting Enzyme (ACE) Inhibitors and Angiotensin II Receptor Blockers (ARBs)

Pregnancy

Glucagon-like Peptide 1 Agonist

- Hypersensitivity
- Type 1 diabetes
- Treatment of diabetic ketoacidosis

Synthetic Analog of Human Amylin

- Hypersensitivity
- Poor compliance with current insulin regimen
- Poor compliance with prescribed self-blood glucose monitoring

- A1c greater than 9%
- Recurrent severe hypoglycemia requiring assistance during the past 6 months
- Presence of hypoglycemia unawareness
- Confirmed diagnosis of gastroparesis
- Requiring the use of drugs that stimulate gastrointestinal motility
- Requiring the use of drugs that slow the intestinal absorption of nutrients
- Pediatric patients

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These clinical guidelines are designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients and are not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition. A guideline will rarely establish the only approach to a problem.
- This clinical guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients are urged to consult a health care professional regarding their own situation and any specific medical questions they may have.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Once a guideline is approved for release, a member group can choose to concentrate on the implementation of that guideline. When four or more groups choose the same guideline to implement and they wish to collaborate with others, they may form an action group.

In the action group, each medical group sets specific goals they plan to achieve in improving patient care based on the particular guideline(s). Each medical group shares its experiences and supporting measurement results within the action group. This sharing facilitates a collaborative learning environment. Action group learnings are also documented and shared with interested medical groups within the collaborative.

Currently, action groups may focus on one guideline or a set of guidelines such as hypertension, lipid treatment, and tobacco cessation.

Detailed measurement strategies are presented in the original guideline document to help close the gap between clinical practice and the guideline recommendations. Summaries of the measures are provided in the National Quality Measures Clearinghouse (NQMC).

Key Implementation Recommendations

The implementation of type 2 diabetes mellitus clinical guidelines at medical groups and clinics is a complex and challenging task. However, a number of key

processes have been shown to accelerate effective clinical guideline implementation and care improvement. These overlapping care elements can be categorized at the medical group and provider levels:

- Essential Elements at the Medical Group Level
- Essential Elements at the Clinic Level

Refer to the original guideline document for detailed information regarding key implementation recommendations.

IMPLEMENTATION TOOLS

Clinical Algorithm
Pocket Guide/Reference Cards
Quality Measures

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

RELATED NQMC MEASURES

- Diagnosis and management of type 2 diabetes mellitus: percentage of adult patients who have had a screen for A1C, LDL less than 100 mm/dL, blood pressure less than 130/80, who are current documented non-smokers and take daily aspirin.
- Diagnosis and management of type 2 diabetes mellitus: frequency of low-density lipoprotein (LDL) cholesterol values in adult patients with type 2 diabetes mellitus by category: less than 100 mg/dL, 100-130 mg/dL, greater than 130 mg/dL, incalculable, untested.
- Diagnosis and management of type 2 diabetes mellitus: percentage of adult patients with type 2 diabetes mellitus with A1C measured in the last six months.
- Diagnosis and management of type 2 diabetes mellitus: percentage of adult patients with type 2 diabetes mellitus with microalbumin tested within last 12 months.
- Diagnosis and management of type 2 diabetes mellitus: percentage of adult patients with type 2 diabetes mellitus with eye exam documented within last 12 months.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Diagnosis and management of type 2 diabetes mellitus in adults. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2008 Mar. 89 p. [126 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1996 Mar (revised 2008 Mar)

GUIDELINE DEVELOPER(S)

Institute for Clinical Systems Improvement - Private Nonprofit Organization

GUIDELINE DEVELOPER COMMENT

Organizations participating in the Institute for Clinical Systems Improvement (ICSI): Affiliated Community Medical Centers, Allina Medical Clinic, Altru Health System, Aspen Medical Group, Avera Health, CentraCare, Columbia Park Medical Group, Community-University Health Care Center, Dakota Clinic, ENT Specialty Care, Fairview Health Services, Family HealthServices Minnesota, Family Practice Medical Center, Gateway Family Health Clinic, Gillette Children's Specialty Healthcare, Grand Itasca Clinic and Hospital, HealthEast Care System, HealthPartners Central Minnesota Clinics, HealthPartners Medical Group and Clinics, Hutchinson Area Health Care, Hutchinson Medical Center, Lakeview Clinic, Mayo Clinic, Mercy Hospital and Health Care Center, MeritCare, Mille Lacs Health System, Minnesota Gastroenterology, Montevideo Clinic, North Clinic, North Memorial Care System, North Suburban Family Physicians, Northwest Family Physicians, Olmsted Medical Center, Park Nicollet Health Services, Pilot City Health Center, Quello Clinic, Ridgeview Medical Center, River Falls Medical Clinic, Saint Mary's/Duluth Clinic Health System, St. Paul Heart Clinic, Sioux Valley Hospitals and Health System, Southside Community Health Services, Stillwater Medical Group, SuperiorHealth Medical Group, University of Minnesota Physicians, Winona Clinic, Ltd., Winona Health

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GUIDELINE COMMITTEE

Committee on Evidence-Based Practice

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Work Group Members: Bruce Redmon, MD (Work Group Leader) (University of Minnesota) (Division of Endocrinology); JoAnn Sperl-Hillen, MD (Work Group Leader) (HealthPartners Medical Group) (Internal Medicine); Richard Bergenstal, MD (Park Nicollet) (Endocrinology); Steve Smith, MD (Mayo Clinic) (Endocrinology); Patrick O'Connor, MD (HealthPartners Medical Group) (Family Medicine); Julie Roberts, MS, RD, CDE (HealthPartners Medical Group) (Health Education); James Brosseau, MD (Altru Health System) (Internal Medicine); Kari Fabian, MD (North Clinic) (Internal Medicine); Eugene Ollila, MD (Allina Medical Clinic) (Internal Medicine); Carol Manchester, MSN, APRN (Fairview Health Services) (Nursing); Deb Perry, RN (Olmsted Medical Center) (Nursing); Vyvy Vo, PharmD (HealthPartners Medical Group) (Pharmacy); Penny Fredrickson (Institute for Clinical Systems Improvement) (Measurement Advisor); Melissa Marshall, MBA (Institute for Clinical Systems Improvement) (Facilitator); Cally Vinz, RN (Institute for Clinical Systems Improvement) (Facilitator)

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

ICSI has adopted a policy of transparency, disclosing potential conflict and competing interests of all individuals who participate in the development, revision and approval of ICSI documents (guidelines, order sets and protocols). This applies to all work groups (guidelines, order sets and protocols) and committees (Committee on Evidence-Based Practice, Cardiovascular Steering Committee, Women's Health Steering Committee, Preventive & Health Maintenance Steering Committee, Respiratory Steering Committee and the Patient Safety & Reliability Steering Committee).

Participants must disclose any potential conflict and competing interests they or their dependents (spouse, dependent children, or others claimed as dependents) may have with any organization with commercial, proprietary, or political interests relevant to the topics covered by ICSI documents. Such disclosures will be shared with all individuals who prepare, review and approve ICSI documents.

Richard Bergenstal, MD has stock in Merck through a family inheritance.

James Brosseau, MD received speakers' fees or honorarium from Merck and NovoNordisk.

Kari Fabian, MD received research or grant funding from NovoNordisk and received speakers fees or honorarium from Bayer. Dr. Fabian received gifts from NovoNordisk and Merck.

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No other work group members have potential conflicts of interest to disclose.

ICSI's conflict of interest policy and procedures are available for review on ICSI's website at www.icsi.org.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Institute for Clinical Systems Improvement (ICSI). Management of type 2 diabetes mellitus. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2006 Nov. 82 p.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Institute for Clinical Systems Improvement (ICSI) Web site.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org; e-mail: icsi.info@icsi.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Diagnosis and management of type 2 diabetes mellitus in adults. Executive summary. Bloomington (MN): Institute for Clinical Systems Improvement, 2008 Mar. 1 p. Electronic copies: Available from the Institute for Clinical Systems Improvement (ICSI) Web site.
- ICSI pocket guidelines. May 2007 edition. Bloomington (MN): Institute for Clinical Systems Improvement, 2007.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org; e-mail: icsi.info@icsi.org.

PATIENT RESOURCES

None available

NGC STATUS

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